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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.								
10/586,310	05/31/2007	Maria Margarita Garcia-Calvo	059893-0121	2509								
210 MERCK P O BOX 2000 RAHWAY, NJ 07065-0907	7590 06/14/2010		<table border="1"><tr><td colspan="2">EXAMINER</td></tr><tr><td colspan="2">HAQ, SHAFIQUL</td></tr><tr><td>ART UNIT</td><td>PAPER NUMBER</td></tr><tr><td>1641</td><td></td></tr></table>		EXAMINER		HAQ, SHAFIQUL		ART UNIT	PAPER NUMBER	1641	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/586,310	<b>Applicant(s)</b> GARCIA-CALVO, MARIA MARGARITA	
	<b>Examiner</b> SHAFIQL HAQ	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,7-10 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,7-10 and 21-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/25/06, 3/17/08 and 12/23/08</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Election-Restriction***

1. Applicants' election of a single species of a compound for "substituted 2-azetidinone glucuronide" in response of to Office Action of January 22, 2010 is acknowledged and entered.
2. Claims 1, 7-10 and 21-25 are pending and examined on merits in this office action.

### ***Information Disclosure Statement***

3. The NPL documents that have been lined through in the IDS filed 10/25/2006 have not been considered because dates are missing for citations. Proper correction is required in accordance with 37 CFR 1.98. Each publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant pages of the publication, date, and place of publication.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1,7-10 and 21-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. The recitation "detectably labeled substituted 2-azetidinone glucuronide compound selected from the group consisting of compound 1, compound 2, compound 8 and the compound of Formula IIa" in claim 1 renders the claim

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indefinite because the claim does not itself define the invention but rely on external material and modern claim practice requires that the claim must stand alone to define the invention and incorporation into claims by express reference to the specification is not permitted (Ex parte Fressola, 27 USPQ 2d 1608). The omission of failing to describe the claimed invention renders the claim incomplete.

7. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation compound of Formula IIa, and the claim also recites compound 2, which is the narrower statement of the range/limitation of compound of Formula IIa. As for example, in the compound of Formula IIa, R<sup>11</sup> can be -SO<sub>2</sub>-C<sub>1-3</sub>alkyl and R<sup>12</sup> can be

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glucuronide or glucuronide ester, which are broader limitations than the compound 2, wherein R<sub>11</sub> is -SO<sub>2</sub>-CH<sub>3</sub> and R<sub>12</sub> is glucuronide. Therefore, presence of both the broader and narrower limitation in the same claim makes the claim indefinite.

8. In claim 1, the compound of Formula IIa can be selected from wherein (i) R<sup>9</sup>= -CC-CH<sub>2</sub>-NR<sup>10</sup>R<sup>11</sup> wherein R<sup>11</sup> can be -SO<sub>2</sub>-C<sub>1-3</sub>alkyl or -SO<sub>2</sub>-phenyl or (ii) R<sup>9</sup>= -CC-CH<sub>2</sub>-NR<sup>10</sup>R<sup>11</sup> wherein R<sup>11</sup> can be -SO<sub>2</sub>-C<sub>1-3</sub>alkyl or -SO<sub>2</sub>-phenyl. In either of the alternative selection, the compound could be the same and therefore, it is unclear what applicants are intended to encompass by repetition of the same embodiment in the claim.
9. With regard to claim 1, it is unclear what compound is referred to by the compound 8 in the specification because specification discloses compounds 8a (see page 113) and compound 8b (see page 114) but not compound 8.
10. With regard to claim 24, the compound 7 of the claim does not read on the compounds of claim 1 as claimed.
11. Claim 1 recites "wherein said modulation indicates that the candidate compound is a ligand that binds to human NPC1L1". The detectably labeled substituted 2-azetidinone glucuronide compound is used as a competitor in the competitive binding but however, the method steps in the claim does not require detection of the detectably labeled substituted 2-azetidinone glucuronide compound that is bound to NPC1L1 to determine modulation of binding of the detectably labeled substituted 2-azetidinone glucuronide compound to human NPC1L1 for determining whether the candidate

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compound is a ligand for NPC1L1. Further it is also unclear as to modulation with respect to what?

### ***Conclusion***

12. No claims are allowed.

13. The prior art made of record that are not relied upon is considered pertinent to applicant's disclosure.

The closest prior art of record (Altman *et al* US 7,135,556 B1) teach substituted azetidinone (e.g. ezetimibe) as target for NPC1L1 but fail to teach glucuronidated ezetimibe as a target for NPC1L1.

Heek *et al* (British Journal of Pharmacology 2000) teach glucuronidated ezetimibe as cholesterol absorption inhibitor but fail to teach glucuronidated ezetimibe as a target for NPC1L1.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shafiqul Haq/  
Primary Examiner, Art Unit 1641